Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHRISTIAN MAYAUD

Appeal No. 2002-1456
Application No. 09/201,107

ON BRIEF

Before McQUADE, NASE, and BAHR, Administrative Patent Judges.

NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 70, 76, 77 and 79 to 84. Claim 85 has been allowed. Claims 71 to 75 and 78 have been objected to as depending from a non-allowed claim. Claims 1 to 69 have been canceled.

We AFFIRM-IN-PART.

BACKGROUND

The appellant's invention relates to a computer-implented prescription management system to assist physicians in prescribing and reviewing drugs (specification, p. 1). A copy of the claims under appeal is set forth in the appendix to the appellant's brief.

Claims 79 to 83 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,542,420 to Goldman et al. (Goldman).

Claim 84 stands rejected under 35 U.S.C. § 102(a) as being anticipated by Faden[1].

Claim 84 stands rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,867,821 to Ballantyne et al. (Ballantyne) in view of Faden.

Claims 70, 76 and 77 stand rejected under 35 U.S.C. § 103 as being unpatentable over Fox[2].

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[1] Article entitled "Privacy and Security of Personal Information in a New Health Care System."

[2] Article entitled "Rxwriter."

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the answer (Paper No. 17, mailed August 28, 2001) for the examiner's complete reasoning in support of the rejections, and to the brief (Paper No. 16, filed June 11, 2001) for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

The anticipation rejection based on Goldman

We will not sustain the rejection of claims 79 to 83 under 35 U.S.C. § 102(e) as being anticipated by Goldman.

Claim 79 reads as follows:

> A computer-implemented patient prescription history record display system having a program embodied on a computer-readable medium, the system being operative to display an electronically generated prescription history of a patient's prior prescribed treatments at multiple record-independent facilities, the prescription history record comprising a patient identifier, a prescribed drug, at least one drug quantifier for the prescribed drug and a treatment date for each

> treatment, wherein the patient history record is a virtual patient record newly assembled online from multiple separate components respectively obtained form multiple remote source databases in response to a system user request for the patient prescription history record.

Goldman's invention relates to a health care system for specifying edibles[3] to individual subjects. The personalized method and system for storage, communication, analysis and processing of health-related data comprises a storage containing data relating to health and edibles and is adapted to receive data on the conditions and characteristics of the individual subjects. The health care system further comprises input terminals adapted to be coupled to the storage means (e.g., database 26) for providing data on the conditions and characteristics of the individual subjects, and a health computer for correlating the data relating to health and edibles with the data on the condition and characteristics of an individual subject to provide a personalized prescription of edibles.

The appellant argues (brief, p. 5) that the claimed "system being operative to display an electronically generated prescription history of a patient's prior prescribed

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[3] The term "edible" as used in Goldman encompasses substances taken orally, including various nutritives and food substances, such as vitamins, minerals and so on, as well as pharmaceutical substances, such as various drugs used for the treatment of chronic, as well as acute clinical conditions.

treatments at multiple record-independent facilities" is not readable on[4] Goldman's single database 26. We agree. While Goldman's single database 26 receives data from multiple record-independent facilities, this data is stored in database 26 for later retrieval. Thus, Goldman would display an electronically generated prescription history of a patient's prior prescribed treatments at multiple record-independent facilities based on data currently stored in the database 26 and not from data newly assembled online from multiple separate components respectively obtained form multiple remote source databases in response to a system user request for the patient prescription history record as required in claim 79.

Since all the limitations of claim 79, and dependent claims 80 to 83, are not met by Goldman for the reasons set forth above, the decision of the examiner to reject claims 79 to 83 under 35 U.S.C. § 102 is reversed.

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[4] A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). The inquiry as to whether a reference anticipates a claim must focus on what subject matter is encompassed by the claim and what subject matter is described by the reference. As set forth by the court in Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984), it is only necessary for the claims to "'read on' something disclosed in the reference, i.e., all limitations of the claim are found in the reference, or 'fully met' by it."

The anticipation rejection based on Faden

We will not sustain the rejection of claim 84 under 35 U.S.C. § 102(a) as being anticipated by Faden.

Claim 84 reads as follows:

> A patient data access control software system for implemented on a computer for screening users attempting to access a patient history data whereby, only pre-authorized users can access patient data, wherein access control is maintained by reference to record-access specifications provided in a security profile in a pre-authorization file the pre-authorization file being used to control access to the patient's data and wherein the record-access specifications determining which parties can access what data during what period of time.

The appellant argues (brief, p. 7) that Faden does not disclose ". . . access control is maintained by reference to record-access specifications provided in a security profile in a pre-authorization file . . ." as recited in claim 84. We agree. We have reviewed Faden's article (especially page 8 cited by the examiner) but fail to find any structure therein which would meet the above-noted limitation of claim 84. Specifically, while Faden does teach providing secure access to health information by limiting access to authorized persons at authorized times, Faden does not teach maintaining access control by reference to **record-access specifications provided in a security profile in a pre-authorization file**.

Since all the limitations of claim 84 are not met by Faden for the reasons set forth above, the decision of the examiner to reject claim 84 under 35 U.S.C. § 102 is reversed.

The obviousness rejection of claim 84

We sustain the rejection of claim 84 under 35 U.S.C. § 103 as being unpatentable over Ballantyne in view of Faden.

Ballantyne's invention relates to a method and apparatus for distribution and administration of medical services, entertainment services, electronic health records, and educational information useful in hospitals, other types of health care facilities, and patients' homes. The medical information network consists of all the related hardware and software components of a master library (ML) (2), a communications interconnection system (4), the distributed processing nursing stations (6), individual bedside patient care stations (PCS) (8), and integrated personal data assistants (PDA) (10). Figure 1 is a schematic block diagram of the overall system. The ML, situated locally within the physical boundary of each hospital or by geographical regions serving several hospitals, is configured as a client/server system and acts as a medical data depository for all text, audio, and video material including text, graphics, still images, full motion video, and sound/audio information. The ML includes the storage and

processing capabilities to satisfy all administration, medical staff, and patient service requirements.

The types of data stored in the ML include: (a) all patient/medical staff health record information, (b) all clinical data including such items as X-Ray, MRI video images, etc., (c) all patient laboratory data to support medical diagnosis and investigations, (d) educational/training information in video and/or textual format for the training of medical personnel and patient requirements, (e) pharmaceutical databases, (f) entertainment audio/video data, (g) monitored video of critical areas including operating rooms, psychiatric wards, etc., (h) general security video monitoring data, and (i) management information data including account/billing and inventory control/ordering services.

Ballantyne teaches (column 7, line 66, to column 8, line 64) that

> [t]he complete ML is implemented within an unique security architecture (48). The security process is based on the identification and authentication of individuals requesting access to the health record database. This access can be requested internally or from external sources. Access is only granted to authorized users of which the library software automatically audits all users' accesses. Patients request or are sent a monthly statement illustrating who has had access to their health records. Various levels of security access are applied to different sections of the individual's health record i.e. psychiatric data can not be accessed by the general practitioner. The other aspect of the security shell deals with the data compression technology. Depending on the format of the data, different compression algorithms are used. This forms another level of security for without the correct decompression algorithm to undo the original

compression operation, the data remains unusable. FIGS. 9A, 9B, and 9C illustrate the security screening access process that is implemented when a new user attempts to gain access (320) to the ML and the medical information network. Initially, each potential user of the network has completed a questionnaire that identifies who they are and specific demographics about them. Once successfully completed, an unique identification number (ID) is assigned to each user and their personal profile data is stored electronically online. Users are subdivided into specific categories relative to their qualifications, their professional status, and their necessity to gain access to medical information and/or the medical information network i.e. physicians as compared to nursing staff, ambulance personnel as compared to medical staff, surgeons as compared to psychiatrists, etc. To gain access to the medical information network, each user first enters their ID number (322). This ID number is then validated (324) with a central user list to confirm they are a legitimate user. If a match does not occur they are immediately denied system access (326). However, if a match is determined, the users personal electronic profile is accessed (328). The system then queries (330) the user with a specific question (332) i.e. What was your mother's name? If the user answers correctly (334), access to the network is granted (336) and the time of access is logged (344). This completes the user identification and authentication process. However, for each access attempt the user makes, the authentication query changes based on the information in the user's personal electronic profile. The validated user is now allowed to access the patient's electronic medical record. Depending on the category classification of user's ID number as previously discussed, general access (338) to the patient's record is granted or a further Personal Identification Number (PIN) is requested (340). This would occur in the situation where a patient's general practitioner would like to review the patient record to determine the latest status and would not have access to sensitive psychiatric data within the patient's record. This area could only further be accessed upon entry of another user's number (342) i.e. psychiatrist's unique PIN. As well as logging the access time of each user on the network, each patient record has its own audit trail. All authorised users that access any patient record, their name and time of access are all documented (344). The patient has the right to request an access log (346) for their personal medical record or the system can initiate a timely print out (348) of all active personal medical records which is forwarded to patient for review. When the authorised user has completed their requirement for accessing the medical network, a standard exit log-off procedure (350) is initiated If for any reason the user forgets to log-off the network, their access is automatically terminated after a duration of 12 hours.

In this rejection of claim 84 under 35 U.S.C. § 103, the examiner (answer, p. 4) appears to have ascertained[5] that (1) the only difference between Ballantyne and claim 84 is the limitation concerning authorized access at authorized times (i.e., the record-access specifications provided in the security profile in the pre-authorization file determining which parties can access what data during what period of time) and (2) it would have been obvious to one having ordinary skill in the art at the time of the invention to have implemented a condition of authorized access at authorized times in the system of Ballantyne as suggested and taught by Faden's teachings since the time limitation (i.e., at authorized times) would provide further protection of the computer records in the system.

The appellant argues (brief, pp. 7-9) that the examiner has not presented a proper case of obviousness as required under 35 U.S.C. § 103 since (1) neither Ballantyne nor Faden teach or suggest "a pre-authorization file" as recited in claim 84, and (2) there is no motivation to combine Ballantyne and Faden. We do not agree.

In our view, Ballantyne teaches "a pre-authorization file" as recited in claim 84 except for controlling an authorized parties' access to the patient's data during a period

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[5] After the scope and content of the prior art are determined, the differences between the prior art and the claims at issue are to be ascertained. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

of time. In that regard, Ballantyne teaches that (1) access to patient data is only granted to authorized users due to the library software automatically auditing all users' accesses, (2) various levels of security access are applied to different sections of the individual's health record (e.g., psychiatric data can not be accessed by the general practitioner), (3) an unique identification number (ID) is assigned to each user and their personal profile data is stored electronically online, (4) users are subdivided into specific categories relative to their qualifications, their professional status, and their necessity to gain access to medical information and/or the medical information network (e.g., physicians as compared to nursing staff, ambulance personnel as compared to medical staff, surgeons as compared to psychiatrists, etc), (5) to gain access to the medical information network, each user first enters their ID number which ID number is then validated with a central user list to confirm they are a legitimate user, and (6) a validated user is allowed to access the patient's electronic medical record, however, depending on the category classification of the user's ID number either general access to the patient's record is granted or a further Personal Identification Number is requested to obtain complete access to the patient's electronic medical records. Thus, Ballantyne's computer system stores more that just a central user list to control access to the patient's electronic medical records. The claimed access control being maintained by reference to record-access specifications provided in a security profile in a pre-authorization file is, in our view, readable on the data stored on Ballantyne's

system that determines the extent of a valid user's access to a patient's electronic medical records (e.g., the unique identification number assigned to each user, the personal profile data stored for each user including the data the user is entitled to view without a valid PIN).

In applying the test for obviousness,[6] we reach the conclusion that it would have been obvious at the time the invention was made to a person of ordinary skill in the art to have combined the teachings of Ballantyne and Faden in the manner set forth by examiner. In that regard, the teachings of Faden to secure access to health information by limiting access to authorized persons at authorized times would have provided sufficient motivation,[7] in our opinion, to a person of ordinary skill in the art at the time the invention was made to have modified Ballantyne's system to likewise secure access to the health information stored on the system by limiting access to authorized persons at authorized times.

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[6] The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. See In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).

[7] We note that while there must be some teaching, reason, suggestion, or motivation to combine existing elements to produce the claimed device, it is not necessary that the cited prior art specifically suggest making the combination (see B.F. Goodrich Co. v. Aircraft Braking Systems Corp., 72 F.3d 1577, 1583, 37 USPQ2d 1314, 1319 (Fed. Cir. 1996) and In re Nilssen, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988)). Rather, as stated above, the test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art.

For the reasons set forth above, the decision of the examiner to reject claim 84 under 35 U.S.C. § 103 is affirmed.

The obviousness rejection of claims 70, 76 and 77

We will not sustain the rejection of claims 70, 76 and 77 under 35 U.S.C. § 103 as being unpatentable over Fox.

Claims 70 and 76 read as follows:

> 70. A prescription creation software system implemented on a computer comprising a program embodied on a computer-readable medium, the system being for use by a prescriber to create an electronic prescription prescribing a drug treatment for a patient condition exhibited by a patient at a point-of-care, the patient having a drugs benefit provider, the drugs benefit provider issuing a prescription benefit plan including a drug formulary for the patient listing at least one drug preferred by the drugs benefit provider for treatment of the condition, the electronic prescription comprising a patient identifier, at least one prescribed drug and at least one drug quantifier for the prescribed drug and being usable by a pharmacist to dispense the prescribed drugs or drugs, the prescription creation system providing:
>
> a) a prescription creation screen display, permitting prescriber-operable data capture including:
>
> i) patient-identifying data;
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> ii) prescribed drug identification data;
>
> iii) drug quantification data; and
>
> b) a library of prescribed drug data accessible from the prescription creation screen to display multiple prescribable drugs; and
>
> c) drug formulary information identifying at least one of multiple drugs as a patient's drug formulary preferences to enable selection by the prescriber of a benefit plan recommended drug;
>
> by which the patient's drug formulary preference may be presented to the prescriber prior to completion of the prescription.

76. A prescription creation software system implemented on a computer having a program embodied on a computer-readable medium, the system being for use by a prescriber to create an electronic prescription prescribing a drug treatment for a patient at a point-of-care, the electronic prescription comprising a patient identifier, at least one prescribed drug and at least one drug quantifier for the prescribed drug and being usable by a pharmacist to dispense the prescribed drugs or drugs, the prescription creation system providing:

a) a prescription creation screen display, permitting prescriber-operable data capture of information including:

i) patient-identifying data;

ii) prescribed drug identification data;

iii) drug quantification data; and

b) a prescription output device to output a prescription completed with patient, prescribed drug and prescribed drug quantifier information;

and comprising a drug contraindication review routine automatically activatable from the prescription creation system prior to dispatch of the completed prescription for fulfillment, the drug contraindication review routine accessing contraindication information regarding the prescribed drug and generating an alert regarding a relevant such contraindication.

Fox is an evaluation review of the software prescription writing program Rxwriter. The review provides that several efficiencies are not incorporated into Rxwriter including (1) there is no distinction or cross-referencing between generic and brand names, (2) no prescription library is supplied, and (3) no drug-interaction checking.[8]

[8] The evaluation does note that the software program SOAP Drug Interaction and Prescription Writer does have automatic interaction flagging. However, it is not clear from this article whether the SOAP Drug Interaction and Prescription Writer program can meet all the limitations of claim 76 (e.g., the limitations set forth in paragraph a)).

In the rejection of claims 70, 76 and 77[9] under 35 U.S.C. § 103, the examiner (answer, p. 5) appears to have ascertained that (1) the Rxwriter program lacks the drug contraindication review routine as recited in claim 76 and the drug formulary information (i.e., paragraph c)) and library (i.e., paragraph b)) limitations of claim 70 and (2) it would have been obvious to one having ordinary skill in the art at the time of the invention to have improved the Rxwriter program by incorporating therein the inefficiencies noted by Fox.

The appellant argues (brief, pp. 9-12) that the examiner has not presented a proper case of obviousness as required under 35 U.S.C. § 103 since there is no motivation to have modified the Rxwriter program to arrive at the subject matter of claims 70, 76 and 77. We agree.

Obviousness is tested by what the teachings of the applied prior art would have suggested to those of ordinary skill in the art. However, teachings of the applied prior art can be combined only if there is some suggestion or incentive to do so. ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). Here, it is our opinion that Fox does not contain sufficient suggestion or incentive for an artisan to have modified the Rxwriter program to arrive at the subject

[9] Claim 77 is dependent on claim 76.

matter of claims 70, 76 and 77. In our view, the inefficiencies noted by Fox, at most, may have suggested that one skilled in the art might have found it obvious to try to incorporate those inefficiencies into the Rxwriter program. However, whether a particular combination might be "obvious to try" is not a legitimate test of patentability. See In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988); In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 379 (Fed. Cir. 1986); In re Antonie, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977).

Instead, it appears to us that the examiner relied on hindsight in reaching his obviousness determination. However, our reviewing court has said, "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." W. L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). It is essential that "the decisionmaker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made . . . to

occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." Id.

For the reasons set forth above, the decision of the examiner to reject claims 70, 76 and 77 under 35 U.S.C. § 103 is reversed.

CONCLUSION

To summarize, the decision of the examiner to reject claims 79 to 84 under 35 U.S.C. § 102 is reversed; the decision of the examiner to reject claim 84 under 35 U.S.C. § 103 is affirmed; and the decision of the examiner to reject claims 70, 76 and 77 under 35 U.S.C. § 103 is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

JOHN P. McQUADE
Administrative Patent Judge

JEFFREY V. NASE
Administrative Patent Judge

) BOARD OF PATENT
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) AND
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BAHR, Administrative Patent Judge, concurring-in-part and dissenting-in-part:

While I join in the remainder of the majority's decision, I cannot join in the majority's reversal of the examiner's rejection of claims 70, 76 and 77 as being unpatentable over Fox. While I concur with the majority's reversal of the rejection of claim 70, I dissent from their decision to reverse the rejection of claims 76 and 77. My reasons follow.

With respect to claim 70, I concur in the result (i.e., reversal of the rejection) reached by the majority, but my reasons therefor differ from those expressed by the majority. Quite simply, I find no mention of formulary information, as called for in claim 70, in Fox and thus no teaching or suggestion to incorporate such a feature into the Rxwriter program.

Appellant's sole argument (brief, page 11) with respect to claim 76 is that Fox does not teach or suggest "a drug contraindication review routine automatically activatable from the prescription creation system prior to dispatch of the completed prescription for fulfillment, the drug contraindication review routine accessing contraindication information regarding the prescribed drug and generating an alert regarding an relevant such contraindication." In reversing the examiner's rejection, the majority agreed with appellant, reasoning that Fox's criticism of the Rxwriter software as

missing the efficiency of the ability to combine drug-interaction checking with prescription writing, at most, may have suggested that one skilled in the art might have found it obvious to try to incorporate that inefficiency into the Rxwriter program. As pointed out by our reviewing court in In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988), obviousness does not require absolute predictability of success; all that is required is a reasonable expectation of success. The case before us is not one of the type discussed in O'Farrell involving unpredictable arts wherein there is no evidence suggesting that the modification would be successful. Indeed, in this instance, Fox points out that prescription-writing software (the SOAP Drug Interaction and Prescription Writer) with a drug interactions flagging feature had been developed prior to appellant's invention, thereby evidencing that one of ordinary skill in the art at the time of appellant's invention would have understood how to incorporate such a feature into prescription-writing software and suggesting that the modification proposed by the examiner would be successful. From my perspective, Fox's criticism of the Rxwriter software as lacking the automatic drug-interaction checking feature, praise for the SOAP Drug Interaction and Prescription Writer software as having an automatic drug interactions flagging feature and criticism of the SOAP Drug Interaction and Prescription Writer software as having an unwieldy interface as compared with the Rxwriter software would have fairly suggested to one of ordinary skill in the art combining the advantageous features of both software packages by providing in the

more user-friendly Rxwriter software a drug interaction flagging feature as called for in claim 76.

For the foregoing reasons, I would sustain the examiner's rejection of claim 76 as being unpatentable over Fox. As for the rejection of claim 77 as being unpatentable over Fox, appellant's only argument against this rejection is that the additional feature set forth in dependent claim 77 is not disclosed by Goldman. Inasmuch as appellant has not argued that this feature is not taught or suggested by Fox, the reference relied upon by the examiner, I would sustain the rejection of this claim as well.

In light of the majority's reversal of the rejections of claims 70, 76 and 77, the examiner may wish to consider the patentability of these claims in light of the teachings of the Halvorson patent (U.S. Pat. No. 4,847,764, issued July 11, 1989), already of record in the application, which was submitted by appellant as part of an information disclosure statement (Paper No. 20). Halvorson discloses a system for entering prescriptions at a physician console and for dispensing the drugs prescribed at dispensing locations. The system utilizes a database comprising drug information (column 8, lines 5-31) including generic and brand names and formulary indicator, generic drug information (column 8, lines 32-68) including generic drug name and drug interaction codes, patient identification information (column 9, lines 51-68) including

patient identification number, date of birth, personal data and description of allergies, and patient history and medication history information (column 10, line 1 et seq.). As disclosed in column 2, line 53, and column 4, lines 47-55, Halvorson's system includes automatic drug-interaction and allergy warnings. Additionally, the examiner should consider investigating the SOAP Drug Interaction and Prescription Writer software mentioned in the Fox reference (note footnote 8 in the majority's decision) to see whether the subject matter of claims 70, 76 and 77 is patentable thereover.

JENNIFER D. BAHR
Administrative Patent Judge

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